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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,341	08/01/2003	Stephen Alan Jobling	1770D.	3594

7590 06/28/2006
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EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,341

Applicant(s)

JOBLING ET AL.

Examiner

Brent Page

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 29-31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>08/01/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 32 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/01/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 29-31 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of producing starch comprising modifying any characteristic of any plant comprising introducing into the plant any combination of sequences wherein each sequence encodes an enzyme having any starch synthase activity and also wherein the combination of sequences comprise a gene encoding potato starch synthase II enzyme and a gene encoding potato starch synthase III enzyme. The claims are further drawn to a plant comprising starch with a

Art Unit: 1638

reduced viscosity onset temperature by at least 12 degrees Celsius compared to starch extracted from equivalent, unmodified plants.

In contrast, the specification only provides guidance for the transformation of a potato plant with a construct containing partial cDNAs of potato starch synthase II and potato starch synthase III wherein the plant has a reduced viscosity onset temperature and does not provide guidance for the transformation of any other plant species with any other starch synthases or any other embodiments of potato starch synthase II or potato starch synthase III.

The effect of starch synthase genes on starch content and structure is unpredictable. Recent studies have shown that GBSSI genes in many plant species have more than one isoform, and further that different isoforms are present in different plant tissues and therefore have different effects on the starch content of the endosperm. Patron et al (Plant Physiology 2002, 130: 190-198) disclose a study detailing the altered pattern of amylose accumulation in low-amylose barley cultivars with mutant alleles of the different isoforms of barley GBSSI (see page 190 1st full paragraph, page 191, last full paragraph, page 192, last full paragraph). Edwards et al (The Plant Cell 2002, 14: 1767-1785) disclose the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full paragraph, page 1768 1st and second full paragraphs, page 1771 3rd full paragraph, and page 1775 in its entirety). Absent a specific SEQ ID number, the claims necessarily encompass multitudes of starch synthase genes, mutated and otherwise, from multiple sources, but also within a single source (ie potato) which have not been disclosed in the

Art Unit: 1638

specification, and in any event, would be unpredictable in their effect on the starch content and structure of the plant. Undue experimentation would be required to isolate and evaluate the effects of all the starch synthase genes on starch content and structure in a heterologous transgenic plant.

The effect of a gene transformed into a different plant background is unpredictable when it is related to specific biosynthetic pathways peculiar to particular plant species. The claims do not specify the plant species that is being transformed. It is inherent that there are multitudes of plant species that have not been evaluated for starch production and have not been evaluated for the presence of the genes and enzymes for starch biosynthesis. For this reason, it is unpredictable what the effect of transforming these multitudes of plant species with potato starch synthase II and potato starch synthase III would be, and undue experimentation would be required to evaluate all plant species for transformation and starch content of the starch produced.

Salehuzzaman et al (1999, Plant, Cell and Environment 22:1311-1318) conducted a study in which a cassava GBSSI gene was transformed into an amylose-free potato. Salehuzzaman et al found that amylose content was only partially restored (see page 1313 second full paragraph, for example).

Furthermore it is unclear how one of skill in the art would obtain a plant comprising starch with a reduced viscosity onset temperature compared to the starch of equivalent, unmodified plants as broadly claimed in claim 29. The claim encompasses embodiments in which the claimed plant is unmodified, and no guidance is given on how to obtain such a plant. Undue experimentation would be required of one of skill in

Art Unit: 1638

the art to evaluate all plants for reduced viscosity onset temperature compared to all equivalent plants.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate all starch synthase genes from all sources as claimed. Undue experimentation would have also been required to obtain and evaluate a multitude of potato starch synthase II and potato starch synthase III nucleotide sequences for their ability to alter starch content and structure in all plants as broadly claimed. Undue experimentation would have also been required to isolate and evaluate every starch synthase gene capable of producing starch with the desired modified content and structure as claimed. The Federal Courts have determined that a significant number of inoperative embodiments is deemed to indicate an undue amount of experimentation (see *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

Claims 25, 29-31 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of producing starch comprising modifying any characteristic of any plant comprising introducing into the plant any combination of sequences wherein each sequence encodes an enzyme having any

Art Unit: 1638

starch synthase activity and also wherein the combination of sequences comprise a gene encoding potato starch synthase II enzyme and a gene encoding potato starch synthase III enzyme. The claims are further drawn to a plant comprising starch with a reduced viscosity onset temperature by at least 12 degrees Celsius.

In contrast, the specification only provides guidance for the transformation of a potato plant with a construct containing partial cDNAs of potato starch synthase II and potato starch synthase III wherein the plant has a reduced viscosity onset temperature and does not provide guidance for the transformation of any other plant species with any other starch synthases or any other embodiments of potato starch synthase II or potato starch synthase III.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

Art Unit: 1638

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties".

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 29-31 and 33-35 are rejected under 35 U.S.C. 102(a) as being anticipated by Lloyd et al (1999 Biochem. J. 338:515-521).

The claims are broadly drawn to a method of producing starch comprising modifying any characteristic of any plant comprising introducing into the plant any combination of sequences wherein each sequence encodes an enzyme having any starch synthase activity and also wherein the combination of sequences comprise a gene encoding potato starch synthase II enzyme and a gene encoding potato starch synthase III enzyme. The claims are further drawn to a plant comprising starch with a reduced viscosity onset temperature by at least 12 degrees Celsius compared to starch extracted from equivalent, unmodified plants.

Lloyd et al teach a potato plant transformed with a genetic construct comprising a sequence encoding a potato starch synthase II enzyme and a sequence comprising a potato starch synthase III enzyme wherein the starch content was modified as evidenced by visualization of distorted starch granules (see page 516 first paragraph and page 517 last full paragraph, for example). The reduced viscosity onset

Art Unit: 1638

temperature is an inherent property of a potato transformed with an antisense construct of both SSII and SSIII.

Claims 25, 30, and 32-35 rejected under 35 U.S.C. 102(b) as being anticipated by Block et al (WO9745545).

The claims are broadly drawn to a method of producing starch comprising modifying any characteristic of any plant comprising introducing into the plant any combination of sequences wherein each sequence encodes an enzyme having any starch synthase activity.

Block et al teach the transformation of wheat plant with genetic constructs comprising nucleic acids that encode enzymes with starch synthase activity, wherein the starch content of the plant is altered (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph pages 13 last paragraph page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half of page, page 29 in its entirety, for example). The Examiner is interpreting the phrase "or sequences functionally equivalent thereto" to read on any starch synthase activity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 29-31 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al (WO9745545).

The claims are broadly drawn to a method of producing starch comprising modifying any characteristic of any plant comprising introducing into the plant any combination of sequences wherein each sequence encodes an enzyme having any starch synthase activity and also wherein the combination of sequences comprise a gene encoding potato starch synthase II enzyme and a gene encoding potato starch synthase III enzyme. The claims are further drawn to a plant comprising starch with a reduced viscosity onset temperature by at least 12 degrees Celsius compared to starch extracted from equivalent, unmodified plants.

Block et al teach genetic constructs comprising altered nucleic acids that encode enzymes with starch synthase activity and disclose the alteration of starch content (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph pages 13 last paragraph page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half of page, page 29 in its entirety, for example). Block et al state "Moreover, the present invention also relates to transgenic plant cells transformed with **one or more** nucleic acid molecules of the invention" (see page 13 last paragraph). Block et al also state "Compared with wild-type starch, such starch may be modified in particular with respect to its viscosity and/or the gel formation properties of the glues of this starch".

Given the state of the art, and the disclosure by Block et al, it would have been obvious to one of ordinary skill in the art to modify the method taught by Block et al by

Art Unit: 1638

transforming more than one nucleic acid encoding enzymes of starch synthase activity into a plant to achieve a plant producing starch wherein the viscosity onset temperature is reduced by at least 12 degrees centigrade.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/632,341
Art Unit: 1638

Page 12

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.